

II. REMARKS

This paper is filed in response to the Office Action dated September 28, 2009, in connection with the above-identified patent application.

Claims 1-29 are pending. Claims 17-29 are withdrawn.

By this amendment, claims 1 and 12 are amended. Support for the amendments can be found in the specification and claims as originally filed. For example, support for claim 1 can be found in the specification at least on page 9, line 15-16. Claim 12 has been amended to correct informalities and to depend properly from claim 7. Applicants submit that no new matter has been added.

Information Disclosure Statement

The Examiner states that the Information Disclosure Statement (IDS) filed on October 7, 2005, has not been considered because of the alleged failure to comply with 37 CFR § 1.98(a)(3). Specifically, the Examiner asserts that the IDS does not comply with 37 CFR § 1.98(a)(3), because it does not include a concise explanation of the relevance of foreign language documents.

Applicants respectfully submit that the Examiner's position is incorrect in view of the Manual of Patent Examining Procedure (MPEP) §609.04(a), which states that a search report in a counterpart foreign application meets the requirement of a concise explanation of a foreign language document. In this case, Applicants submit that an English language search report was filed along with IDS on October 7, 2005. Therefore, Applicants submit that the IDS complies with 37 CFR § 1.98(a)(3) and request reconsideration by the Examiner.

Rejection under 35 U.S.C. §112

Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Office Action stated that there is insufficient antecedent basis for the phrase "the hydrolysing and alkylating composition."

Applicants have amended claim 12 to properly depend on claim 7. Applicants submit that present claim 12 has proper antecedent basis.

Rejection under 35 U.S.C. §103

Claims 1-16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Schul et al. (WO 01/72136 published October 4, 2001, hereinafter "Schul") in view of Bonakdar et al. (U.S. Patent Application Publication No. 2002/0082434, published June 27, 2002, hereinafter "Bonakdar").

Present claim 1 is directed to a "process for the production of a sterol fatty acid ester-rich composition comprising the steps of:

- (a) combining
 - a sterol composition, comprising one or more sterols,
 - a fatty acid glyceride composition, comprising glycerol fatty acid esters of one or more fatty acids, and
 - an esterification catalyst to form a reaction mixture,
- (b) performing esterification of sterol(s) in said reaction mixture to produce a sterol fatty acid ester containing mixture,
- (c) adding a hydrolysatation catalyst and an alkylating component to hydrolyse mono-, di- and/or triglycerides present therein and to produce corresponding fatty acid alkyl ester(s) and glycerol, and
- (d) purifying the sterol fatty acid ester containing mixture to form a sterol fatty acid ester-rich composition" (emphasis added). Claims 2-16 depend from claim 1.

Applicants submit that the cited references do not teach or suggest the presently claimed invention. For example, Applicants submit that Schul discloses a process for preparing a sterol ester composition including reacting sterols with lower alkyl fatty acid esters in the presence of a catalyst. See page 8, lines 8 to 10. However, Applicants submit that Schul does not teach or suggest the unexpected results found with the presently claimed invention, which is a process for the production of a sterol fatty acid ester-rich composition comprising a step (a) of "combining... a sterol composition..., a fatty acid glyceride composition, comprising glycerol fatty acid esters of one or more fatty acids, and an esterification catalyst to form a reaction mixture" (emphasis added). Applicants note that the presently claimed invention provides "an efficient and rapid process for the production of a sterol ester-rich composition." See page 5, lines 4-5. The specification explains that by using fatty acid glycerides, there remains incompletely reacted mono-, di-, and triglycerides after the first reaction step. Thus, a subsequent step of hydrolyzing the glycerides provides reactive fatty acid alkyl esters that may be recycled to the first

reaction step to provide an excess of reactive fatty acid derivatives into the esterification of sterols. The specification discloses that this excess of fatty acid esters enables optimal conversion levels in the esterification of sterols even if only about a stoichiometric input of new fatty acid components, in glyceride form, is provided in a continuous batch process. See page 11, lines 23 to page 12, line 2. Furthermore, the specification discloses that the hydrolyzation of glycerides minimizes the amount of mono-, di- and triglycerides in the final sterol fatty acid ester product, thereby creating a pure sterol fatty acid ester-rich product. See page 12, lines 3 to 8. Additionally, the specification states that the invention provides a simple, efficient, and cost effective food grade process for providing a sterol fatty acid ester rich composition because it utilizes fatty acids present in glycerides, which are available on the market. Thus, there is no need to purchase or separately prepare the fatty acid or fatty acid alkyl ester components because the fatty acid alkyl ester components may be derived from the corresponding glyceride compositions. See page 20, lines 14 to 27.

Therefore, Applicants submit that while Schul may broadly disclose reacting a lower alkyl fatty acid ester, Applicants have discovered the aforementioned advantages in using fatty acid glycerides, which are esters of glycerol and fatty acids.

Applicants further note that Schul, in Example 1, discloses the preparation of methyl fatty acid esters with fatty acids from canola oil. Further, Example 2 discloses the use of methyl fatty acid ester for the esterification of sterol. Applicants note that the methyl fatty acid ester is produced in a separate, first reaction (or is commercially acquired), whereas the presently claimed process starts with the fatty acid glycerides directly.

Applicants submit that Bonakdar does not fulfill the deficiencies of Schul. Applicants submit that Bonakdar discloses the isolation of free sterols from an oil distillate residue. Applicants submit that one of ordinary skill in the art would not consider Bonakdar when developing a method of esterification of free sterols to sterol fatty acid esters. For example, Applicants note that Bonakdar discloses a method which starts with a composition comprising 10-12% sterol esters. A first transesterification step is performed and other components are thereby made more easy to remove, and then finally the sterol esters are transesterified to free sterols which are purified. Applicants submit that Bonakdar, like Schul, fails to teach or

suggest the above-described unexpected results found with the presently claimed invention, which involves a step (a) of combining a sterol composition, a fatty acid glyceride composition, and an esterification catalyst.

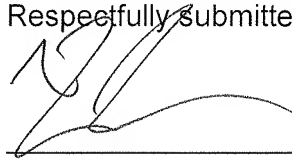
For at least the above reasons, Applicants respectfully submit that the presently claimed invention is patentable over Schul and Bonakdar. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-16 under 35 U.S.C. § 103(a) over Schul and Bonakdar.

III. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 019075-00071.

Respectfully Submitted,



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